



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231  
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/914,066      | 08/23/2001  | Hisakazu Katsuki     | KATSUKI=1           | 8579             |

1444 7590 10/01/2002

BROWDY AND NEIMARK, P.L.L.C.  
624 NINTH STREET, NW  
SUITE 300  
WASHINGTON, DC 20001-5303

EXAMINER

WARE, TODD

ART UNIT PAPER NUMBER

1615

DATE MAILED: 10/01/2002

5

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/914,066

Applicant(s)

KATSUKI, HISAKAZU

Examiner

Todd D Ware

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 November 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### DETAILED ACTION

Receipt of preliminary amendment filed 8-23-01 and information disclosure statement filed 11-21-01 is acknowledged. The amendment to the specification referencing the international application PCT/JP00/00862 has been entered. Claims 1-17 are pending.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:  
  
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. **Claims 1-14 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**
3. The word general, appearing in the recitation of the dihydrobenzofuran derivative in claim 1, is indefinite as it is assigned to a specific structure. Deletion of this word would overcome this rejection.

#### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1615

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. **Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borkan et al (4,935,243; hereafter '243) in view of Cynshi et al (WO 97/17066; hereafter '066 –US 6,103,753 is relied upon as a translation of '066).**

7. '243 teaches hermetically sealed soft gelatin capsules (seamed soft gelatin capsules) filled with a vegetable oil such as soybean oil that deliver a water insoluble active agent (4-(2-nitrophenyl)-2,6-dimethyl-3,5-dicarbomethoxy-1,4-dihydropyridine AKA nifedipine). The shell of '243 also contains sorbitol and glycerin as plasticizers.

8. '066 teaches capsules for the instant active agents to treat arteriosclerosis.

9. Accordingly, absent a demonstration of criticality, it would have been obvious to one skilled in the art at the time of the invention to combine the above references with the motivation of providing an oral means for administering the hydrophobic active agent of '066 in a dosage form that provides a carrier for the active agent. The limitations requiring concentrated glycerin are not considered critical since the glycerin is ultimately diluted with the gelatin/sorbitol/glycerin formulation. Upon addition of the concentrated glycerin, the concentrated glycerin becomes diluted. Therefore,

Art Unit: 1615

concentrated glycerin does not appear to be critical in the absence of a demonstration of criticality.

10. **Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borkan et al (4,935,243; hereafter '243) in combination with Cynshi et al (WO 97/17066; hereafter '066 –US 6,103,753 is relied upon as a translation of '066) and further in combination with Demichele et al (6,013,665; hereafter '665.**

11. '243 and '066 are relied upon for all that they teach as stated previously.

12. '665 further elaborates on teachings *supra*, teaching that the absorption of lipophilic compounds is enhanced by concurrent administration of the lipophilic compound and an oil such as soybean oil.

13. Accordingly, absent a demonstration of criticality, it would have been obvious to one skilled in the art at the time of the invention to combine the above references with the motivation of enhancing the oral delivery of the instant lipophilic active agent.

Limitations requiring concentrated glycerin are not considered critical since the glycerin is ultimately diluted with the gelatin/sorbitol/glycerin formulation. Upon addition of the concentrated glycerin, the concentrated glycerin becomes diluted. Therefore, concentrated glycerin does not appear to be critical in the absence of a demonstration of criticality.

***Conclusion***

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

tw  
September 27, 2002

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600